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**General Surgical Innovations, Inc.
3172A Porter Dr.
Palo Alto, CA. 94304**

SMDA Summary
Attachment B

510(K) SUMMARY

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

Summary of Safety and Effectiveness

Contact Person

Theresa M. Nazaroff
General Surgical Innovations, Inc.
3172A Porter Dr.
Palo Alto, CA
94304

Device Name

Mammary Sizer

Substantial Equivalence and Conclusions

The Mammary Sizer which is proposed for use in the sub-glandular of sub-muscular tissue plane is substantially equivalent to Mentor's Volume Sizer for Mammary Implants that are marketed for use in the area of plastic and reconstructive surgery.

Intended Use

The GSI, Inc. Mammary Sizer is intended to assist in evaluation of the appropriate mammary prosthesis volume for each patient prior to implantation.

Device Description

The GSI Mammary Sizer is designed to be used during plastic and reconstructive surgery when it is desirable to determine the correct volume and/or symmetry of mammary implants prior to implantation. The device is constructed of smooth semi-elastomeric polyurethane. The device consists of a balloon and balloon tubing used for filling the sizer. There is an attachment to prevent fluid leakage and a female luer lock at the proximal end of the filler tube.

Testing Results and Conclusions

Testing performed to support the appropriateness of the Mammary Sizer for its intended use include biocompatibility, material strength, and volume rating.


Theresa M. Nazaroff

General Surgical Innovations, Inc.

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